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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,970	09/26/2001	Horst Lindholfer	080575-00000	1046

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EXAMINER

HELMS, LARRY RONALD

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,970

Applicant(s)

LINDHOLFER ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1 and 17, 19, 21 have been amended.  
Claims 37-38 have been added.
2. Claims 1-38 are under examination.
4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
5. The following Office Action contains some NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

6. The rejection of claims 1-36 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
8. The rejection of claims 2-3, 24-27 under 35 U.S.C. 103(a) as being unpatentable over Berd (US Patent 6,458,369, with priority to 5/98) and further in view of Lindhofer et al [a] (Blood 88:4651-4658, 1996, IDS 9/26/01) and Lindhofer et al [b] (US Patent 6,551,592, filed 9/97) and Multihoff et al (Int. J. Cancer 61:272-279, 1995) and Jedlitschky et al (US Patent 6,235,785, 2/97) is withdrawn in view of arguments.

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***Response to Arguments/NEW GROUNDS of rejection***

8. The rejection of claims 1, 4-23, 28-36 and newly added claims 37-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Berd (US Patent 6,458,369, with priority to 5/98) and further in view of Lindhofer et al [a] (Blood 88:4651-4658, 1996, IDS 9/26/01) and Lindhofer et al [b] (US Patent 6,551,592, filed 9/97) and Multihoff et al (Int. J. Cancer 61:272-279, 1995) and Jedlitschky et al (US Patent 6,235,785, 2/97) is maintained.

The response filed 2/22/05 has been carefully considered but is deemed not to be persuasive. The response states that the examiner has not pointed out where in the cited references one might find that there is a time interval between the administration of the tumor cells and the antibodies although Berd references the word "consecutively" the Webster's dictionary states that "consecutively" means "following one after the other in order without a gap", thus all the limitations have not been met in claim 1 (see page 13 of response). In response to this argument, as stated Berd teach administration "consecutively" which means "one after another" and as such the claims do not require a specific time interval and as such "consecutively" broadly would read on the claims and would be a time interval between administration.

The response states that Lindhofer(b) describe simultaneous binding to a tumor cell thus this reference teaches away (see page 14 of response). In response to this argument, Lindhoffer (b) does not teach away because although the antibodies have to bind tumor cells, the tumor cells there is no requirement as to when they are administered.

The response further states that the basis of Lindhoffer (b) is that the antibody, T cell and tumor cell requires the simultaneous presence of the tumor cells and the antibodies and this is the surprising discovery of the instant invention that a time staggered fashion can induce anti-tumor immunity (see page 14 of response). In response to this argument, Berd specifically teaches administration of the tumor cells to elicit an immune response and induce T cells to target the tumor cells and in view of Lindhoffer (b) it would have been obvious to add the bispecific antibody after one induced the T cells because Lindhoffer's antibodies bind tumor cells and T cells and it is obvious that one needs T cells to target the tumor cells as taught in Lindhoffer (b).

Thus, it would have been obvious to add treated tumor cells prior to administration of a bispecific antibody with the characteristics claimed because the tumor cells increase the T cells and the bispecific antibodies bind the T cell and the tumor cells to initiate an immune response against the tumor.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

10. The rejection of claims 1-36 and newly added claims 37-38 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/378218 is maintained.

The response filed 2/22/05 has been carefully considered but is deemed not to be persuasive. The response states that the pending instant claims should be allowed and the rejection withdrawn (see page 14 of response). In response to this argument,

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the claims in the instant case are not allowed and the double patenting rejection is maintained.

***Conclusion***


11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832



LARRY R. HELMS, PH.D  
PRIMARY EXAMINER